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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,305	02/23/2006	James M. Davenport	SALTER P47AUSP1	1903

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,305	DAVENPORT ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *20-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/24/07, 9/25/07, 2/6/09 & 3/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Election of Group I, claims 1-19 filed October 23, 2009. No claims were amended, cancelled, or added; thus, claims 1-43 are pending in this application.

Election/Restrictions

2. Applicant's election of Group I, claims 1-19 in the reply filed on October 23, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7-9 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The terms "substantially" and "generally" in claims 7-8 and 17-18 are relative terms which render the claims indefinite. The term "substantially" and "generally" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

apprised of the scope of the invention. Regarding claims 7 and 17, it is unclear how "sufficiently short" the axial length must be to "substantially" span no more than a width of a philtrum of a patient, particularly given the size of patients varies with age. Regarding claims 8 and 18, it is unclear how "curved" the bends of the supply lines must be to "conform generally with a curvature of a face of a patient" particularly given facial curvature would vary based on age, sex, and ethnicity of a patient.

6. Regarding claims 9 and 19, it is unclear what "sufficient stiffness" is required so as to "urge" the attached auxiliary respiratory gas supply line to pass beneath a patient's cheekbone area and it is unclear what is meant by the term "urge" in the claims.

.Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Agdanowski et al., (4,648,398).

Regarding claim 1, Agdanowski discloses a nasal cannula (figure 1) for supplying a respiratory gas (12) to a patient (abstract), the nasal cannula (figure 1) comprising: a pair of supply lines (18 & 20) which each have a head (30 & 32) at one end thereof with a discharge opening (46 &48) therein for discharging a respiratory gas (oxygen), and the opposite end (22) of each of the pair of supply lines being connectable (capable of being connected) to a respiratory gas source (12); wherein each head (30 &32) is sized

so that it would be snugly received and retained (col. 1, lines 47-51) within one of the nasal cavities of the patient (the hexagon shape which would inherently form voids at the concaved portion) which would form a sufficient leakage passage (via hexagon shapes and voids created therefrom), between a portion of inwardly facing nasal cavity skin of a patient and a potion of an exterior surface of the head (concaved portions of hexagon as shown in figure 4), to facilitate exhausting of any excess respiratory gas supplied to the patient (upon nasal exhalation) through the leakage passage and the voids created would also facilitate inhalation of any room air required in excess of the respiratory gas (oxygen) to be supplied to the patient.

Regarding claim 11, Agdanowski discloses a remote end (at connector 22) of each of the auxiliary respiratory gas supply line[s] (18 and 22) is connected with a respiratory gas source (12) for supplying a respiratory gas to a patient (abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 2-10 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agdanowski et al. (4,648,398) in view of Hahn et al. (5,105,807).

Agdanowski discloses all the limitations of claims 2 and 12, except the limitation wherein an exterior surface of the head has a plurality of elongate troughs formed therein for partially defining a plurality of leakage passages therein to facilitate

exhausting of any excess respiratory gas and inhalation of any room air required by the patient.

Kahn teaches a disposable nasal anchoring system with various shapes that can be used as a compressible sleeve and that modifications of the sleeve can be adapted according to need or desirability. See: col. 3, lines 38-46 and figures 4a-4g. Kahn specifically teaches a compressible sleeve (figure 4g) that has an exterior surface (outer surface) of the head (compressible sleeve) has a plurality elongate troughs (formed between ridges) formed therein for partially defining a plurality of leakage passages ("channels can additionally be formed between the outside of the sleeve 8 and the inside of the nostril by irregularly shaped sleeves") therein to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g.

Regarding claims 3 and 13, the exterior surface of the head taught in figure 4g of Kahn has between six and eight elongate troughs (formed between ridges) formed therein which are equally spaced about a circumference of the head, and each of the elongate troughs partially defines one of the leakage passages in the head to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g.

Regarding claim 4 and 14, each of the plurality elongate troughs of Kahn is formed by a pair of adjacent planar side surfaces (sides of exterior walls) which diverge away from a common elongate valley (lowest most point of troughs) toward a pair of spaced apart but adjacent elongate ridges (upper most point of exterior surfaces) to

partially define one of the plurality of leakage passages. See: col. 5, lines 29-43 and figure 4g.

Regarding claims 5 & 6 and 15 & 16, the combined references lack the specific teaching that each one of the leakage passages has a cross sectional open area of between about 0.002 square inches (0.013 cm2) and 0.0055 square inches (0.035 cm2), as claimed in claim 5; or, wherein each head has a maximum width dimension of between about 0.345 of an inch (0.88 cm) about 0.70 of an inch (1.8 cm) and a length of between about 0.30 of an inch (0.76 cm) and about 0.60 of an inch (1.5 cm); however, Kahn specifically describes how modifications of the sleeve can be adapted according to need or desirability and it a change in the size or shape of a prior art device is a design consideration well within the skill of the art.

Regarding claims 7 and 17, the pair of supply lines of Agdanowski are connected with one another by a central bridge member (28) which has a sufficiently short axial length (at the top of 28 which separates 30 from 32) that spans substantially no more than a width of a philtrum of the patient, when in use.

Regarding claims 8 and 18, the nasal cannula of Agdanowski is manufactured from a flexible material (col. 1, line 59 - col. 2, line 2 of Agdanowski); and a second end of each of the supply lines bends away (50 and 52 in figure 1 of Agdanowski) from one another and is curved so as to conform generally with a curvature of a face of a patient, when in use.

Regarding claims 9 and 19, the bends in the second end of each of the supply lines of Agdanowski is coupled to an auxiliary respiratory gas supply line (18 & 20 of

Agdanowski), and the ends of each of the supply lines is sufficiently stiff to urge the attached auxiliary respiratory gas supply line (18 & 20 of Agdanowski), coupled thereto, which when worn by a patient would have the supply lines (18 & 20 of Agdanowski) to pass beneath a patient's cheekbone area when the nasal cannula is donned by a patient.

Regarding claim 10, Agdanowski discloses a central bridge member (28) that aligns the pair of supply lines parallel to one another to facilitate insertion of the heads (30 & 32 of Agdanowski) within the nostrils of the patient. See: figure 1 of Agdanowski.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weichselbaum (4,790,308) discloses a nasal cannula.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771